OEvidera Unlocking the Potential of Interoperable, Linked, Low-latency National Health Data in England to Protect Vulnerable Patients while Safeguarding their Privacy: A Brave New World

Justo N^{1, 2*}; Taylor S³; Antonarou A⁴; Lu Y⁵; Dube S³; Ejaz M⁴; Evans K⁶; Talarico C⁷; Olson V⁵; Kasan J⁴; Turner D⁵

¹Evidera Ltd., part of PPD clinical research, a business of Thermo Fisher Scientific, Stockholm, Sweden; ²Karolinska Institute, Stockholm, Sweden; ³AstraZeneca, Cambridge, UK; ⁴National Health Service England, London, UK; ⁵Evidera Ltd., part of PPD clinical research, a business of Thermo Fisher Scientific, London, UK; ⁶Evidera Inc., part of PPD clinical research, a business of Thermo Fisher Scientific, Waltham, MA, USA; ⁷AstraZeneca, Gaithersburg, MD, USA

Background and Objective

- National Health Service (NHS) England routinely collects national healthcare data, which is provisioned for research for approved investigators to access for permitted projects. Despite this wealth of data, the timely, secure, and continuous access during and after the COVID-19 pandemic challenged the traditional data sharing model.
- Evidera and AstraZeneca piloted NHS England's Secure Data Environment (SDE), part of the NHS Research SDE Network, for their burden of COVID-19 study (INvestigation oF cOvid-19) Risk among iMmunocompromised populations [INFORM], ISRCTN53375662).
- We aim to present this unique public-private collaboration on data access as a case study.

Data Access for Analyses

• Figure 3 provides an overview of data accessed within the SDE and the process for data management, analysis, quality control, compliance checks, and export of results for dissemination.

Figure 3. Overview of Data Sources and Data Access Model



PRIMARY CARE General Practice Extraction Service Data for Pandemic Planning and Research (GDPPR)



SECONDARY CARE Hospital Episode Statistics (HES): admitted patient care, critical care, outpatient care, and emergency care

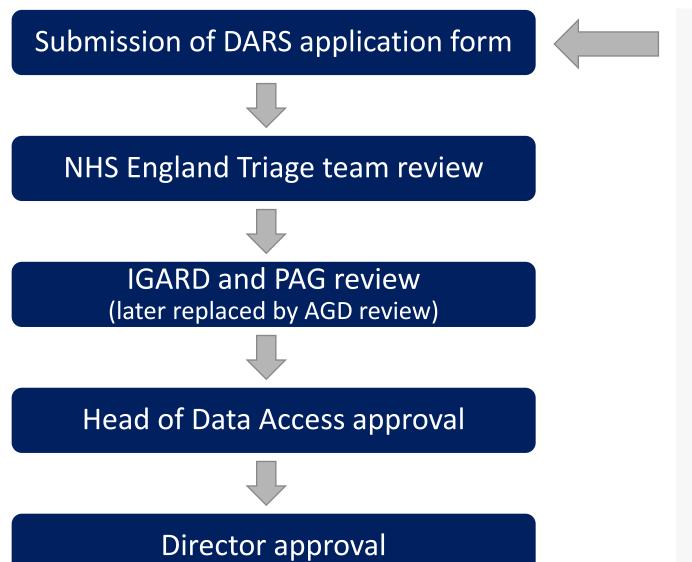
PPD

RWD188

Data Application Process

- Applicants are required to provide details and substantiate compliance with all normative provisions and assurances pertaining to information technology security, data protection, and risk management (Figure 1).
- Access to primary care data from the General Practice Extraction Service (GPES) had never been granted to private entities, so additional scrutiny and safeguards were exacted for this application.
- Thus, the INFORM study became a great fit to pilot NHS's new SDE.

Figure 1. Overview of Data Application Process



- Supporting information and documentation required
- Evidence of adequate security assurance for all data controllers and data processors
- ICO registration details for all data controllers and processors
- Data flow chart
- Project protocol
- Funding approval document if project is not self-funded
- Sublicensing documents as per the sublicensing standard, if applicable
- Confirmation of contract with sub-processors, if any involved

Additional documentation requested

Data risk assessment

Abbreviations: AGD = Advisory Group for Data; DARS = Data Access Request Service; ICO = Information Commissioner's Office; IGARD =

Independent Group Advising on the Release of Data; NHS = National Health Service; PAG = Profession Advisory Group

1. RATIONALE AND GOALS

in poorer outcomes



COVID-19 TESTS COVID-19 Second Generation Surveillance System (SGSS)

VACCINATIONS

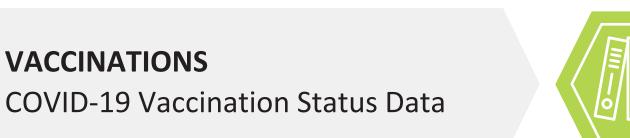
Study-Data

Processor

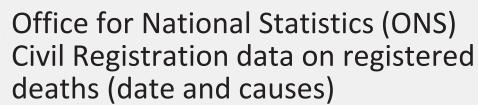
Evidera | PPD



Community dispensing data from the NHS Business Service Authority (BSA)





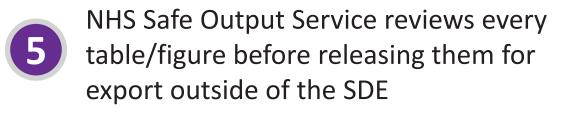


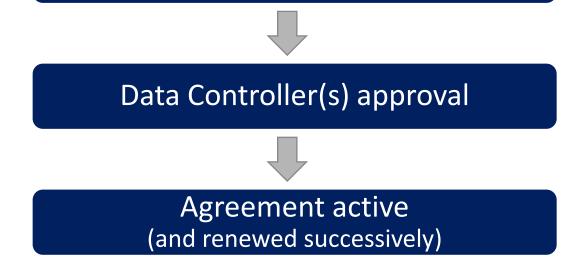
Sponsor determined study goal and purpose of data processing

Evidera developed the protocol and 2 submitted applications (see Figure 1)

Once approved, NHS sorted the study 3 cohort and extracted data into the dedicated INFORM SDE cluster

Evidera runs analyses and code QC, applies suppression and rounding, and submits outputs to NHS





- Data Protection Impact Assessment
- Legitimate interest assessment
- Project-specific privacy notice



Study-Data

Controller

Data

Custodian

NHS England

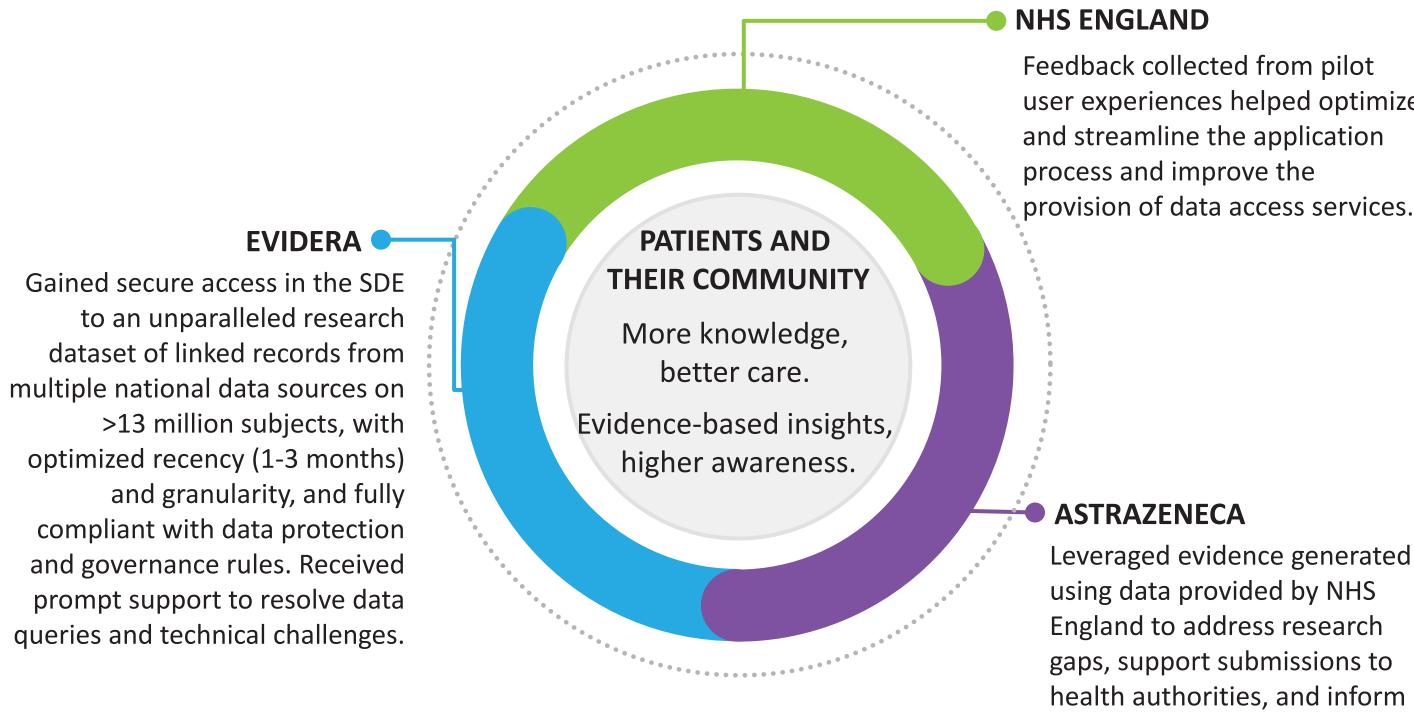
5

Once approved, Evidera exports outputs, 6 conducts additional QC, and shares aggregated results with AstraZeneca for dissemination

Abbreviations: NHS = National Health Service; QC = quality control; SDE = secure data environment

Benefits for Each Stakeholder

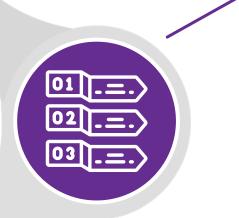
EVIDERA



Feedback collected from pilot user experiences helped optimize and streamline the application process and improve the provision of data access services.

strategic planning.

• The INFORM study aimed to provide a comprehensive assessment of the burden of COVID-()



Overview of INFORM Study

Figure 2. Overview of the INFORM Study

2. METHODS AND MATERIALS

19 among immunocompromised and other vulnerable groups

• Immunocompromised individuals comprise a heterogeneous population, presenting with

suboptimal response to vaccines, and at higher risk of contracting COVID-19 that also result

- Observational study estimated the burden of COVID-19 among vulnerable subgroups, and compared with the general population
- Using 5+ billion linked health records with minimal lag on a 25% random sample of England's population

Abbreviations: NHS = National Health Service; SDE = secure data environment



3. MAIN ACHIVEMENTS

• Study findings were incorporated into dossiers for submission to health authorities (e.g., EMA, Medicines and Healthcare products Regulatory Agency, National Institute for Health and Care Excellence), published in Lancet Regional Health Europe,¹ and disseminated through conference abstracts, presentations, and institutional channels.

• Study has raised awareness among healthcare decision-makers (e.g., consultants advised in the McInnes Report), physicians, patients, and their families, as well as informed preventive behaviors and strategies.

References

1. Evans RA, Dube S, Lu Y, et al. Impact of COVID-19 on immunocompromised populations during the Omicron era: insights from the observational population-based INFORM study. *Lancet Reg Health Eur.* 2023;35:100747.

Conclusions

The success of the INFORM study is attributed to the collaboration between various stakeholders, including specialists in science, legal, privacy, information technology, operations, and compliance functions. This unique collaborative experience demonstrated the feasibility of enabling access for the wider research community, generating research evidence that benefits patients and the public without compromising privacy protection. Operational since December 2022, NHS England's SDE continues to expand its technical and service capabilities to enable secure access to health and social care data.

Disclosures/Acknowledgments

Editorial and graphic design support were provided by Michael Grossi and Kawthar Nakayima of Evidera. NJ, YL, KE, VO, and DT are employees of Evidera, part of PPD clinical research, a business of Thermo Fisher Scientific, which received funding for the conduct of the study from AstraZeneca. ST, SD, and CT are employees of, and may hold stock and/or stock options in, AstraZeneca. AA, ME and JK are employees of NHS England.